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Dear Mr. Secretary:

I am writing to express my strong support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a practicing nuclear medicine physician at Elmhurst Memorial Hospital in Elmhurst, IL. I am deeply concerned over the revised 10 CRF 35 regulations as promulgated in April, 1987, particularly as these regulations would now hold any authorized user of byproduct material for medical use to only use such material or constituents of commercially-manufactured kits for radiopharmaceuticals to only prepare or use these kits as precisely described in the FDA-approved package insert. The intent of these package inserts was and is not to prescribe in any precise manner how a practitioner of medicine may use an FDA-approved pharmaceutical or radiopharmaceutical, rather such package inserts serve as a guideline toward one of conceivably many proper uses of a pharmaceutical/radiopharmaceutical. It would seem to be a great over-simplification on the part of NRC to use the package insert as a benchmark document of the only uses, methods of reconstitution, etc., for which a drug may be used. This strict and narrow interpretation of the use of information in a package insert could cause much increased costs for the provision of radiopharmaceuticals to nuclear medicine practitioners in rural areas where the suggested expiration times listed in package inserts may be exceeded but the quality/safety/efficacy of the radiopharmaceutical is not adversely affected. Indeed, information imparted in package inserts was never intended by pharmaceutical/radiopharmaceutical manufacturers to be the ultimate arbiter of proper use in any absolute sense, and given the costs of changing package inserts it is unlikely that radiopharmaceutical manufacturers would be inclined to do so, in order to provide every nuance of effective use or proper reconstitution/preparation of a radiopharmaceutical.

The NRC is enforcing provisions of Part 35 (35.100, 35.200, 35.300) and Part 33.17(a)(4) even though practices proscribed under those parts are in conformity with FDA regulations and State medical and pharmacy practice laws. The enforcement therefore inappropriately interferes with the practice of medicine and pharmacy and contradicts the NRC's own Medical Policy statement against such interference.

The enforcement of the above-cited Parts will lead to higher exposure to radiation to the public when a radiotracer cannot be supplied to a user and alternate methods of patient testing using x-ray studies (i.e. x-ray CT scans, intravenous pyelography, instead of nuclear medicine cerebral perfusion studies or renograms) must be done. Greater costs to taxpayers will ensue if nuclear medicine thallium-201 heart scans cannot be done to decide which patient must have x-ray heart artery angiograms, and instead patients progress directly to the more expensive and dangerous angiogram directly. If it is the intention of the NRC to minimize radiation exposure to the public (and hopefully to do this as low as reasonably achievable), it is dubious that the intention will be fulfilled.

In closing, I implore the Commissioners to adopt the ACNP/SNM Petition for Rulemaking as expeditiously as possible. Please feel free to contact me by mail or telephone (312) 941-4561 should you require additional information.

DS/D

Sincerely,

John W. Laude, M.D., FACNP
Medical Director, Nuclear Med.